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January 14, 2020

**VIA ECF**

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

**Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation**
**Case No. 1:19-md-02875-RBK-JS**

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on January 15.

**1. Expansion of the MDL**

On December 18, 2019, the Judicial Panel on Multidistrict Litigation entered an order expanding the scope of this MDL to include claims relating to the alleged occurrence of nitrosamines in Losartan and Irbesartan. This Court has since asked whether those drugs may be rolled into the MDL by updating the Valsartan-focused document requests, ESI custodian lists, and ESI search term lists the Court approved in December 2019. The expansion of the MDL to include Losartan and Irbesartan raises a number of complexities, such as those described below,

that may impact the efficient management of the MDL. Accordingly, the parties have agreed to meet and confer to discuss the expansion of the MDL, with the hope of submitting a proposal on issues relating to the management of the expanded MDL in advance of the case management conference on January 28.

**(a) Losartan**

Losartan Potassium ("Losartan") is an angiotensin II receptor blocker ("ARB") indicated for the treatment of hypertension and diabetic nephropathy. Losartan Potassium Hydrochlorothiazide ("Losartan HCTZ") is a combination of Losartan and Hydrochlorothiazide, a diuretic indicated for the treatment of hypertension.

In 1995, the Food & Drug Administration ("FDA") first approved Losartan for use in oral tablet form under the name brand COZAAR®, and in fixed dose combinations with Hydrochlorothiazide under the brand name HYZAAR®. In 2010, the FDA approved the first of 37 applications for generic pharmaceutical manufacturers to begin marketing their own Losartan and Losartan HCTZ products. By approving these generic applications, the FDA determined that the generic products were safe and effective, contained the same active ingredient and have the same clinical effect and safety profile as COZAAR® and HYZAAR®. The FDA also determined that the generic products' labels, including the warnings, precautions and contraindications sections, were the same as the previously approved labeling for COZAAR® and HYZAAR®.

On November 8, 2018, Sandoz, Inc. issued the first recall (voluntary) of a Losartan product—one lot of Losartan HCTZ Tablets—when it discovered that the tablets contained trace amounts of an impurity, N-nitrosodiethylamine (NDEA). In the ensuing months, there were 16

more Losartan product recalls (505 lots), manufactured by multiple defendants.[1] Of the 17 Losartan recalls totaling 506 lots, 12 were due to the presence of NDEA in the medications and 15 were due to the presence of N-Nitroso N-Methyl 4-Amino Butyric Acid (NMBA) in the medications. There were no Losartan recalls because of NDMA, the impurity alleged in Valsartan.

Underscoring the negligible risk, if any, posed by the trace amounts of NDEA found in the recalled Losartan medications, in its December 11, 2018 announcement, the FDA urged patients to continue taking their recalled Losartan medications. On February 28, 2019, the FDA announced that the interim acceptable daily intake levels of NMBA in finished dose drug products was 0.96 ppm. However, on March 20, 2019, the FDA announced that due the shortage of Valsartan, the agency would allow the temporary distribution of specific lots of Losartan containing NMBA above the interim acceptable intake limit of 0.96 ppm and below 9.82 ppm. In so doing, the FDA stated that its scientists evaluated the risk of exposure to NMBA at levels up to 9.82 ppm and determined that it presented no meaningful difference in cancer risk over a six-month time period.

Six personal injury complaints and two consumer class action complaints have been filed asserting claims arising out of alleged nitrosamine impurities in Losartan. Five of those cases have been transferred to the MDL. The remaining three of these cases require transfer by the JPML.[2]

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[1] Torrent, McLeod's, Camber, Legacy, and Teva have all recalled certain lots of Losartan.

[2] In addition to these actions, there are five Plaintiffs who initially raised, but subsequently dropped, claims related to Losartan or Irbesartan. In four personal injury actions, the initial complaints identified both Valsartan and Losartan, but the Short Form Complaints identified only Valsartan. Similarly, the initial TPP complaint filed by Maine Automobile Dealers Association, Inc. Insurance Trust ("Maine Auto") raised claims related to Valsartan, Losartan, and Irbesartan. Maine Auto's claims have been superseded by the TPP Master Complaint, which raises only Valsartan-related claims.

**(b) Irbesartan**

Irbesartan is indicated for the treatment of hypertension and high blood pressure associated with diabetic nephropathy. It is an ARB that works to block a substance in the body that causes blood vessels to tighten. Irbesartan works to relax blood vessels in order to reduce blood pressure. Irbesartan and Hydrochlorothiazide ("Irbesartan HCTZ") is a combination of Irbesartan and Hydrochlorothiazide, a diuretic indicated for the treatment of hypertension.

In 2012, the FDA approved the generic version of Irbesartan medication for use under the brand name AVAPRO®, and Irbesartan HCTZ under the brand name AVALIDE®. By approving these generic applications, the FDA acknowledged that the approved generic Irbesartan and Irbesartan HCTZ had the same quality and strength as brand-name drugs and determined that the generic products' labels would include all current safety information and warnings as in the brand drugs' labels. In 2012, the FDA approved the first of 41 applications for generic pharmaceutical manufacturers to begin marketing their own Irbesartan and Irbesartan HCTZ products.

On October 26, 2018, Aurobindo Pharma Limited ("Aurobindo") issued a voluntary recall of Irbesartan due to trace amounts of NDEA. Aurobindo recalled 22 batches of Irbesartan, which were supplied to ScieGen Pharmaceuticals Inc., U.S. ("ScieGen"). On October 30, 2018, Sciegen issued a voluntary recall of Irbesartan tablets at the consumer level due to trace amounts of NDEA contained in Irbesartan API manufactured by Aurobindo. These tablets are labeled as Westminster Pharmaceuticals and Golden State Medical Supply Inc.

On January 18, 2019, Prinston Pharmaceutical Inc. ("Prinston") and Solco Healthcare Inc. ("Solco") issued a voluntary recall of one lot of Irbesartan and seven lots of Irbesartan HCTZ tablets based on information that the Irbesartan API manufactured by Zhejiang Huahai Pharmaceutical ("ZHP") contained trace amounts of NDEA. Prinston announced that it was only recalling lots of Irbesartan that contained NDEA above the approved FDA daily intake levels.

Underscoring the negligible risk, if any, posed by the trace amounts of NDEA found in the recalled Irbesartan medications, in its December 11, 2018 announcement, the FDA urged patients to continue taking their recalled Irbesartan medications.

One personal injury complaint and three consumer class action complaints have been filed asserting claims arising out of alleged nitrosamine impurities in Irbesartan. All four of those cases have been transferred to the MDL.

**(c) Challenges Concerning the Losartan and Irbesartan Claims**

Given differences between Valsartan, Losartan, and Irbesartan, the expansion of the MDL to include claims relating to alleged impurities in Losartan and Irbesartan presents a number of challenges that may affect the rights of parties and impact the management of the MDL, for example:

- Different, and to-be-named, API and/or finished dose manufacturers, wholesalers, distributors, re-packagers, and retailers may be subject to claims relating only to Losartan and/or Irbesartan, and, conversely, some Defendants involved in

Valsartan cases have no connection to or involvement with recalls or litigation concerning Losartan and Irbesartan;[3]

- Class representatives for Irbesartan and Losartan claims must be identified, and Plaintiffs may have to address issues concerning the inclusiveness of Plaintiffs' leadership;
- The scope of the recalls for Valsartan, Losartan, and Irbesartan vary considerably;
- The Valsartan, Losartan, and Irbesartan actions will involve differing and drug-specific design and manufacturing issues;
- Different facilities and ESI/document custodians may be involved in the manufacturing, quality assurance, regulatory, marketing, sales, and distribution functions pertaining to each drug;
- Chronologies for the manufacture, marketing, and recalls of Valsartan, Losartan, and Irbesartan differ, as do each drug's regulatory profile and portfolio;
- The different impurities and permissible levels of impurities allegedly found in Valsartan, Losartan, and Irbesartan respectively potentially involve the consideration of differing risk assessments; and
- Establishing causation and liability in situations where plaintiffs consumed multiple drugs at issue in this MDL creates complexities in the parties' proofs.

[3] Certain potential Defendants are connected to Losartan or Irbesartan products only, and do not currently have any claims against them in the Master Complaints. There are also entities that have produced smaller quantities or only a few lots of Losartan and Irbesartan. It would be prejudicial to involve them in ongoing discovery efforts within the Valsartan context and without any assessment of appropriate scope and/or proportionality.

**(d) MDL Management Issues**

Complexities involved in managing this MDL are compounded by the expansion to include Losartan and Irbesartan. Given the factual differences between the drugs, the alleged impurities, and the scope of the recalls, lumping the three drugs together may undermine the efficiency of the MDL, and adversely impact the Plaintiffs in prosecuting their claims and the Defendants in defending against those claims. The parties have agreed to meet and confer to discuss the management of the MDL in light of its expansion, with the possibility of discussing the management of the MDL with the Court at the CMC on January 28.

**2. Downstream Defendant Discovery**

The various tiers of downstream entities have initiated meet and confer discussions with Plaintiffs' counsel regarding the scope of downstream discovery and Defendant Fact Sheet ("DFS") obligations. On January 9 the Retailer/Pharmacy Defendants and Plaintiffs' counsel held a further meet and confer to discuss proposed areas of inquiry for Rule 34 and DFS discovery. To facilitate that discussion, counsel for the Retailer/Pharmacy Defendants provided Plaintiffs with a set of proposed categories for production that, in their view, reflected the guidance provided by the Court regarding the appropriate scope of discovery and the categories of information that the Retailer/Pharmacy Defendants could realistically produce without undue burden. At the conclusion of the discussion, Plaintiffs agreed to confer internally and to respond with written comments; the Retailer/Pharmacy Defendants await that response, and also await comments on the revised DFS to Retailer/Pharmacy Defendants, which was sent to Plaintiffs on October 23. Separately, the Wholesaler/Distributor Defendants are scheduled to continue their meet and confer with Plaintiffs' counsel on Tuesday, January 14.

At this time, the downstream defendants are hopeful that Plaintiffs will agree to narrow their requests in a manner comporting with the Court's directives during the December 18 telephone conference, and we will apprise the Court regarding any areas on which the Court's guidance may be necessary.

**3. Manufacturer Defendant Fact Sheets**

Now that extensive document requests directed toward the Manufacturer Defendants have been approved by the Court, the Manufacturer Defendants believe that a DFS directed toward their level of the supply chain would be unnecessary, cumulative, and unduly burdensome. All of the information sought through the current draft of the Manufacturer DFS is cumulative of the documents to be produced in response to the finalized document requests. Should the Court find that a Manufacturer DFS is still warranted, the Manufacturer Defendants await Plaintiffs' response to the edits and comments that the Manufacturer Defendants circulated on October 23.

**4. Preservation of Recalled Product**

On October 25, 2019, counsel for Plaintiffs issued a letter demanding that each Defendant, at every level of the supply chain, preserve and hold "any valsartan API or finished dose products" in its current or future possession, "whether or not they are subject to a recall . . . ." and whether or not newly manufactured and shipped. *See* Exhibit A. Plaintiffs further demanded that each defendant respond in writing to advise Plaintiffs regarding the status of all Valsartan in its possession and to provide details regarding what quantity of product each defendant possesses, when it was received, and where it came from.

Owing to concerns regarding clarity, feasibility, and the impact of Plaintiffs' broad demand, Defendants jointly responded to Plaintiffs on December 20, 2019, advising Plaintiffs that

they were unable to comply with Plaintiffs' demands and identifying a number of concerns including interference with the federal regulatory scheme and duplication of discovery that has already been produced or is being negotiated between the parties. *See* Exhibit B. Counsel for Plaintiffs responded on December 23, writing that they disagreed with Defendants concerns and reiterating their demands.[4] *See* Exhibit C.

For the reasons discussed below, and consistent with Defendants' original letter to Plaintiffs, Defendants submit that Plaintiffs' demands run contrary to and frustrate the federal regulatory scheme, and impose an undue burden on each member of the Valsartan supply chain.

**(a) Plaintiffs' Demands Conflict with the Federal Regulatory Scheme for Product Recall and Undermine FDA's Authority**

**(i) Product Recall Under the Federal Scheme**

The recall of pharmaceutical products is governed by FDA regulations and guidance, which address issues including where to send the recalled product, how to handle recalled product, and how to communicate the recall to patients, healthcare providers and downstream entities responsible for distribution of the product. 21 C.F.R. § 7, *et seq.* FDA regulations require that any recall plan include "specific instructions on what should be done with respect to the recalled products," 21 C.F.R. §7.49(c)(iv), and FDA guidance specifically contemplates that FDA will be involved in the final destruction or disposition of any recalled product. *See, e.g.,* FDA Regulatory Procedures Manual: Chapter 7 – Recall Procedures (April 2019), at 22, 37; FDA Guidance for

[4] Plaintiffs' December 23 letter, unlike the first, specifically referenced "Core Discovery" and addressed issues specific to Manufacturer Defendants, raising questions about precisely which Defendants were the intended targets of Plaintiffs' initial letter.

Industry: Product Recalls, Including Removals and Corrections (Nov. 3, 2003). Any recall protocol ultimately is subject to FDA's final review and approval. 21 C.F.R. § 7.42(a)(2).

Once approved, FDA directs that recalling firms conduct the recall in accordance with the approved recall strategy. *Id.* Each downstream entity responsible for the sale or distribution of the product also is expected to "immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to [their] consignees in accordance with paragraphs (b) and (c) of this section." *Id.* at §7.49(d). It is through this coordinated implementation of the FDA-approved recall protocol that manufacturers can ensure that recalled product is removed from the market and handled in a manner consistent with FDA's guidance and expectations.[5]

Plaintiffs' demand that each defendant who now has or later comes into possession of any Valsartan—recalled or not—hold and preserve any such product. This is objectionable for several reasons.

**(ii) Plaintiffs' Demands Conflict with Federal Requirements**

Each manufacturer is required to follow its FDA-approved Valsartan recall protocol. *Id.* at §7.42(a)(2). Though they vary by manufacturer, in general terms, these recall protocols mandate quarantine and, in some cases, destruction of recalled Valsartan to ensure that any such product is removed from public circulation. For downstream entities, standard protocol is to return recalled

[5] *See* U.S. Food and Drug Administration, *Guidance for Industry: Product Recalls, Including Removals and Corrections*, *available at* https://www.fda.gov/safety/industry-guidance-recalls/guidance-industry-product-recalls-including-removals-and-corrections ("[T]he cooperation of manufacturers and distributors in expediting recall activities is vital because of the determination that a distributed product is potentially hazardous to the public or animals and/or is in violation of the Federal Food, Drug, and Cosmetic Act (the Act).") (last updated Aug. 1, 2014).

product to the manufacturer so that the manufacturer can quarantine, test, or destroy the recalled product in a manner consistent with FDA's guidance.

Plaintiffs' demands, as drafted, require each pharmacy, retailer, wholesaler and distributor to hold and preserve each tablet of Valsartan now or later in its possession. Complying with Plaintiffs' demands would require each downstream entity to retain and preserve any recalled product in *direct conflict* with the instruction to return recalled product to the manufacturers, in violation of federal law. *See id.* at §7.49(d). Moreover, maintaining pockets of recalled product at countless stores, distribution centers or warehouses across the country, also means that manufacturers may not be able to terminate their recalls, because they cannot reliably account for or destroy the product in the manner necessary to certify that they have executed a proper product "correction." *Id.* at § 7.3(h).

Plaintiffs' attempt to dictate the handling of FDA-regulated drugs conflicts with and undermines the federal scheme, raising significant concerns regarding preemption. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."). Defendants should not be forced to choose between complying with federal requirements and meeting Plaintiffs' broad discovery demands.

**(iii) Plaintiffs' Demands Undermine Federal Authority Under the Doctrine of Primary Jurisdiction**

Because Plaintiffs' demands undermine the recall procedure envisioned by FDA, they also run afoul of the primary jurisdiction doctrine. Under that doctrine, where an activity is "subject to

an administrative agency's expertise," courts should defer to the "exclusive competence" of that agency. *In re Human Tissue Prods. Liab.*, 488 F. Supp. 2d 430, 432 (D.N.J. 2007) (Martini, J.)

The FDA's primary jurisdiction over the recall process prevents courts from enforcing a request to preserve all recalled products. In *Clark v. Actavis Group HF*, Judge Greenaway considered this same issue. 567 F. Supp. 2d 711 (D.N.J. 2008) (Greenaway, J.). Following an FDA-announced recall of Digitek® based on the presence of the active ingredient in a dose exceeding the amount stated on the label, plaintiffs filed a putative class action against the manufacturers. *Id*. The plaintiffs sought a court order "requiring Defendants to preserve all Digitek® tablets and/or other items returned by consumers as part of the recall." *Id.* at 714. The Court held that the primary jurisdiction doctrine mandated the court's abstention, because Plaintiffs' proposal, if ordered, would interfere with the recall. *Id.* at 718.

As in *Clark*, the doctrine of primary jurisdiction applies here. If the Court were to enforce Plaintiffs' demands and essentially rewrite the recall protocols already implemented by the Defendants it would set a dangerous precedent of interfering with FDA's exercise of its regulatory authority and impeding the coordinated return of recalled product to manufacturers for appropriate handling pursuant to FDA guidance.

**(b) Plaintiffs' Request is Unnecessary and Unduly Burdensome**

Plaintiffs' ability to prove their case does not hinge on the preservation of each and every tablet of Valsartan in existence. The Manufacturing Defendants already have produced documents in Core Discovery documenting testing of the affected Valsartan lots for the presence of nitrosamine impurities. Further, pursuant to federal law, manufacturers of API and finished dose product also must reserve and retain samples from each batch of product produced. *See* 21 CFR

211.170(a)(1) (requiring retention of reserve samples for at least one year after the expiration date of the last lot containing the active ingredient").

Moreover, contrary to what Plaintiffs imply in their December 23 letter, the routine destruction of product subject to recall is not unusual and does not raise "serious" questions about product handling. Destruction of recalled products pursuant to an FDA-approved recall plan is common in product liability litigation. *See, e.g., U.S. v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 582, 585 (D.N.J. 2004) (ordering, within 30 days and under FDA supervision, the destruction of "all BeneFin, SkinAnswer, and MGN-3 in Defendant's possession, custody, or control."); *U.S. v. Kasz Enterprises, Inc.*, 862 F. Supp. 717, 723–24 (D.R.I. 1994) (ordering, with 45 days and under FDA supervision, destruction of the "Solutions 109" products.").

Plaintiffs' demands that each Defendant preserve each and every tablet of Valsartan—whether or not recalled—if implemented, would require each Defendant to devote significant resources—in terms of manpower, finances *and* physical storage—in order to comply, and all for a benefit that has yet to be articulated.

**(c) Plaintiffs' Demands Unnecessarily Interfere with Patient Access to Valsartan**

Finally, Plaintiffs' demands, as drafted, raise serious concerns regarding continued patient access to Valsartan, and whether a pharmacy or wholesaler/distributor must cease distribution or dispensation of Valsartan altogether in order to comply. Plaintiffs' demand is not limited to recalled Valsartan, and is not limited to Valsartan manufactured by the Manufacturer Defendants in this litigation. FDA, however, has explicitly recognized that not all Valsartan is subject to recall, and has instructed patients to continue taking their medication as prescribed, unless instructed

otherwise by their physicians.[6] Implementing Plaintiffs' demands would undermine the FDA's directive and could present serious risk to patients in need of this medication.

Defendants submit that Plaintiffs' attempt to enforce additional discovery burden through their product preservation demands should be denied.

**5. Short Form Complaints Not Properly Filed with MDL Centrality**

At the November 6, 2019 conference, Defendants raised the issue of improperly filed Short Form Complaints ("SFCs"). *See* Defendants' Position Statement for 11/6/19 CMC (Dkt. 287) at 4–7; *see also* Plaintiffs' Position Statement for 11/6/19 CMC (Dkt. 288) at 3 (agreeing that plaintiffs must comply with orders governing SFCs). The Court requested a list of the improperly-filed SFCs and stated an intention to order those Plaintiffs to re-file their SFCs through the MDL Centrality fillable template by a certain date. *See* 11/6/19 Tr. at 27:19–25. A list of improperly-filed SFCs is attached as Exhibit D.

Defendants have also received a Plaintiff Fact Sheet from Constance Graham Garnes, individually and on Behalf of the Estate of George F. Graham, Civ. A. No. 1:19-cv-15429. That case, however, has been remanded to the New Jersey state court. *See* Civ. A. No. 1:19-cv-15429, Dkt No. 3–4.

**6. Plaintiffs' Motions for Extension of Time**

The Court raised the issue of counsel from the Golden Law Firm filing motions for extension of time. The Golden Law Firm has not filed such motions in the MDL docket (Civ. A.

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[6] *See, e.g.,* U.S. Food and Drug Administration, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan (last checked Jan. 12, 2020).

No. 1:19-md-02875) as required by Case Management Order 1, ¶ 10 (Dkt. 18) and has not contacted the Defense Executive Committee related to such extensions.

**7. Status of Defendants' Ongoing Core Discovery Productions**

The Core Discovery Defendants will continue to produce any additional documents falling under the scope of the Court's Core Discovery Order (Dkt. 88) as they become available.

**8. Status of Defendants' Compliance with Order Regarding Testing**

Following the November briefing and argument on the macro discovery issues, the Court ordered Defendants to "identify the types and purposes of the tests done on Valsartan API and Valsartan." Dkt. 303, ¶ 8. In compliance with that order, in December the Manufacturer Defendants each sent Plaintiffs a letter identifying by Bates number the pages of their DMFs and ANDAs that list the types and purposes of testing performed on valsartan API and valsartan. *See, e.g.*, Exhibit E. On December 6, the ZHP Defendants also met and conferred with Plaintiffs to walk them through the cited documents.

Nevertheless, Plaintiffs continue to request that the Manufacturer Defendants *create* lists of testing, insisting that their letters *citing to* lists are insufficient under the Court's order. Plaintiffs' position is unsupported by the Court's order, which requires Defendants to "identify" the testing, not to recreate existing lists. In addition, Plaintiffs' request would amount to requiring the Manufacturer Defendants to retype the lists contained in these documents, which is an unreasonable and unwarranted request. *See, e.g., Harris v. Advance Am. Cash Advance Ctrs., Inc.,* 288 F.R.D. 170, 172 (S.D. Ohio 2012) (to the extent plaintiff asked defendant to create "list" of specified information, request was denied because party is not required to create documents in response to document requests); *Alexander v. Federal Bureau of Investigation,* 194 F.R.D. 305,

310 (D.D.C. 2000) (denying plaintiff's request for the FBI to create lists of persons whose FBI reports were requested by White House, when list did not exist).

**9. Status of Motion to Dismiss filed by Legacy in *Roddey v. Camber, et al.***

Legacy Pharmaceutical Packaging, LLC is a drug repackager in St. Louis, Missouri. Its involvement with Losartan is limited to repackaging bulk product (*e.g.*, 1,000-count containers) into 30-count prescription bottles for Walmart and Kroger, and then returning it to Walmart's or Kroger's distribution centers in States not including New Jersey. Legacy does not buy product from manufacturers or distributors, or sell product to Walmart, Kroger, or direct consumers.

Two Losartan cases filed in federal court have joined Legacy: the *Roddey* case in this Court, No. 1:19-cv-12763; and the *Garrison* case filed in the U.S. District Court for the Eastern District of Michigan, No. 5:19-cv-12536. Legacy was also joined in a Losartan case filed in Cook County Circuit Court, Illinois; Legacy's challenge to personal jurisdiction in that case is pending.

Given the lack of any connection between the *Roddey* claims and New Jersey, Legacy filed a motion to dismiss for want of personal jurisdiction. All five named Plaintiffs live outside the forum (in Florida, California, or Illinois) and none were prescribed, purchased, ingested, or were injured by Losartan in New Jersey. So even if Legacy had purposefully availed itself of New Jersey in some Losartan-related way (it did not), Plaintiffs' claims have no "affiliation with" that activity and there is no jurisdiction over Legacy. *See Bristol-Myers Squibb Co. v. Superior Court of Cal.*, 137 S. Ct. 1773, 1781 (2017) (holding that, absent an "affiliation between the forum and the underlying controversy, . . . specific jurisdiction is lacking regardless of the extent of a defendant's unconnected activities in the State").

Shortly after Legacy filed its motion, the Court terminated the motion to dismiss without prejudice and stayed the case pending a decision by the JPML on an impending motion to expand the MDL to include Losartan. After the JMPL granted that motion in December, Legacy refiled its motion to dismiss in the MDL (Dkt. 333) and cross-filed in the individual case.

Assuming that the Plaintiffs in *Roddey* could show a connection between their claims and New Jersey (by, for example, joining a New Jersey plaintiff), the Court still would lack personal jurisdiction given the absence of any Losartan-related activity by Legacy that targeted New Jersey. Legacy has made this argument in the *Garrison* case in Detroit, for it similarly has no such Losartan-related activity in Michigan. The court ordered the plaintiff (who is pro se) to show cause why the court should not grant Legacy's motion. Plaintiff missed the response deadline but sought an extension until January 16. The JPML's Conditional Transfer Order 16 (for the *Garrison* matter) was entered and stayed January 2, 2020. Legacy's motion to vacate the CTO is due January 21.

Legacy respectfully asks this Court to take up its Motion to Dismiss at the Court's earliest available setting.

Respectfully submitted,

*/s/ Seth A. Goldberg*

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
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